K001709

AUG 31 2000

V. 510(K) SUMMARY

Pioneer Surgical Technologies
510(K) Notification Summary

Trochanteric Reattachment Device (TRD)

Administrative Information

Manufacturer Identification:	Pioneer Surgical Technologies 375 River Park Circle Marquette, Michigan 49855-1781 Telephone: 906-226-9909 Facsimile: 906-226-4443
Official Contact:	Amy Mommaerts Manager, Regulatory Affairs
Date Prepared:	02/15/00

Device Identification

Proprietary Name:	TRD
Common Name:	Trochanteric Reattachment Device
Classification Name and Reference:	Cerclage, Bone Fixation
Regulation Number:	CFR 888.3010
Classification Number:	87JDQ
Device Class:	Class II

Devices on Which Substantial Equivalence is Claimed:

Predicate Device(s): The Dall-Miles Cable Grip System by Howmedica:

1. Dall Miles "Trochanter Cable Grip System" - K844068;
2. Dall Miles "Modified Trochanter Cable Grip System" - K872224;
3. Dall Miles "Trochanter Cable Grip System (Additional Indications)" - K900926

Device Description
The Trochanteric Reattachment Device (TRD) is a low profile oval stabilizer combined with three (3) cable and three (3) crimps of the SDB Cerclage System (K961267). The SDB Cerclage System cables are passed through holes in the TRD around the femur and back through the TRD serving to attach the device to the trochanter for fixation. SDB crimps located in the central groove tie the cable ends together once they are tensioned and crimped by the Synthes Cerclage Tensioner and Crimper.

The TRD shall be offered in two sizes (standard and long) to accommodate the variations in surgical technique and severity level of the osteotomy and or fracture. The TRD is designed with proximal fingers that hook over the superior, proximal portion of the osteotomized trochanter and serve to position the device during fixation. The TRD also displays distal feet that project into the displaced trochanter at the same angle as the proximal fingers and serve to stabilize the displaced trochanter from swiveling about its proximal end posteriorly towards the gluteus muscle insertions. The TRD counteractive forces are directed medially and inferiorly to neutralize the superior and lateral pull of the hip abductors.

The TRD shall be supplied with the stabilizer preloaded with crimps and cable and packaged either STERILE or NON-STERILE as a single-use item. Information concerning the sterile condition is provided in section III, E of this document.

Intended Use
The TRD will be offered in two sizes of stabilizer/cable constructs (standard and long). Each construct shall be indicated for the reattachment of the greater trochanter following osteotomy in total hip arthroplasty. Additionally, the device is used to reattach the greater trochanter following fracture of the greater trochanter. These devices are intended as single use items.

Technological Characteristic Compared to Predicate Device
The TRD has the same double holed crimp and squeezing technique as the predicate Howmedica Dall-Miles Cable Grip System **(K844068, K872224, & K900926)**.

Performance
The TRD's 1.7mm cable constructs and its predicate device Howmedica's Dall-Miles Trochanteric Cable Grip 2.0mm cable constructs each have CoCr cable for the cerclaging material. In previous greater trochanter system testing, the cerclage cable was the primary failure mode. The TRD construct exhibits three (3) 1.7mm cables versus two (2) 2.0mm cables for the Dall-Miles Trochanteric Cable Grip System. Based on the cable material equivalence and the extra cable in the proposed system an at least equivalent comparison has been logically derived from the information available.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2000

Ms. Amy H. Mommaerts
Manager, Regulatory Affairs
Pioneer Surgical Technology
375 River Park Circle
Marquette, Michigan 49855

Re: K001709
Trade Name: Trochanteric Reattachment Device (Standard) and (Long) Model
Regulatory Class: II
Product Codes: JDQ
Dated: May 23, 2000
Received: June 5, 2000

Dear Ms. Mommaerts:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K001709

DEVICE NAME: Trochanteric Reattachment Device

INDICATIONS FOR USE:

The Trochanteric Reattachment Device is indicated for the reattachment of the greater trochanter following osteotomy in total hip anthroplasty.

Additionally, the device is used to reattach the greater trochanter following fracture of the greater trochanter.

The Trochanter Reattachment Device is a single use item.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diane R. Vachon

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K001709

Prescription Use X OR Over-The-Counter-Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)